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inspiration in the science of pharmacovigilance

CONFERENCE REPORT

Uppsala Forum, May 2016

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Uppsala Monitoring Centre

– Building a global safety culture

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Pharmacovigilance's role in rapid access to safer drugs

At Uppsala Monitoring Centre's (UMC) 30th anniversary in 2008, we organised our first research conference for global scientists and pharmacovigilance experts in Uppsala, Sweden, which has been held biennially since 2012. The conference was formerly held in a conventional format with the focus on plenary presentations with Q&A sessions, but Uppsala Forum 2016 aimed instead at creating an arena focused on discussions and new ideas.

With so many conferences competing for the interest and participation of scientists, and tight schedules and budgets presenting further obstacles, it is not easy to assemble a huge audience. However, Uppsala Forum 2016 successfully achieved this, with around 70 attendees from more than 20 countries.

The theme of the conference that took place on 30-31 May 2016 was "Pharmacovigilance's role in rapid access to safer drugs". The need to develop and rapidly deploy new treatments pushes the boundaries of traditional pharmacovigilance and demands new thinking and practices. How can pharmacovigilance contribute to the safety of new drugs when rapid access is of paramount importance?

It was our pleasure and privilege at UMC to welcome a panel of international experts from Europe, Africa, and North America. The panel discussed the challenges that the pharmacovigilance community faces in trying to address the need for faster access to new drugs, while remaining as vigilant as ever in our efforts to minimise risks to patients. Scientists working on new approaches, the industry developing new products, patients depending on fast access to novel medicines, and the pharmacovigilantes working in the field and in regulation have different perspectives, all of which came together in Uppsala.

Uppsala Forum is the premier venue both for cutting-edge research and for identifying practical applications for it. Here, the focus lies on research on one hand, and on practice and policy on the other. Integrating these two areas provides opportunities for exchange on how to use evidence to increase drug safety in many settings, identify new relevant research questions, and develop new collaborations across sectors.

I would like to thank all participants for having filled the space with their ideas, lively discussions, and inspiration on our way forward towards a safe and effective use of medicines.

P. Caduff-Janosa

Pia Caduff-Janosa
Chief Medical Officer, UMC

Agile pharmacovigilance, is that possible?

Dr Marie Lindquist, Director & CEO, Uppsala Monitoring Centre, Sweden

There is mounting pressure from patients for rapid access to new drugs for diseases with few or no treatment options. What are the risks of exposing patients to rapid-access drugs? How far is current safety surveillance practice a bottleneck, unnecessarily hindering the timely approval of new drugs?

The answer to these questions, and to many of the inadequacies of safety monitoring, could lie in a new, flexible, responsive, light-footed, agile pharmacovigilance; a shift away from one-off marketing authorisation towards iterative safety monitoring and evaluation throughout a medicine's life. Currently, regulatory action may take years following the first sign that a treatment is less effective or more harmful than anticipated. This elaborate, cautious process does not serve patients well.

> "Effective safety monitoring must be a facilitator and not a bottleneck in the delivery of new and more effective therapy."

Three profound questions were raised in Dr Lindquist's presentation:

1. How can a genuine, robust social contract be built, in which all stakeholders – in particular patients, carers and health professionals – are willing to take some risks with the promise of greater benefits? How can they be engaged in active, rapid monitoring and evaluation of new treatments?

2. How can agile and iterative work processes and relationships be applied throughout the whole life of medicines?

3. How can methods and technology be developed to make maximum use of big data, including data from wearable devices and patient stories?

It was Dr Lindquist's hope that the meeting will lead to new initiatives and collaborations that will bring people together in the pursuit of a new agenda for pharmacovigilance; one that requires buy-in and commitment from the whole of society, and active engagement and participation from all stakeholders who share the vision of better therapeutic decisions in the use of medicines. She ended her presentation with a warm welcome to the participants and the challenge that we must be brave enough to find new ways of reforming the familiar and embracing the new.

Ethical and methodological considerations for pharmacovigilance with accelerated release of medicines

Dr Alex John London, Professor of Philosophy & Director,
Centre for Ethics and Policy, Carnegie Mellon University, USA

The ethical and moral grounds for accelerated release of medicines were discussed during Dr London's presentation. Dr London laid out some of the pitfalls of accelerated access, and some of the challenges they pose to the current drug development system. By doing so, he presented the challenges for pharmacovigilance as we move forward on the accelerated access path. During his talk he addressed the shortcomings of individually focused moral arguments for further accelerating access, introduced ethical and scientific concerns about early access in order to highlight challenges for pharmacovigilance, and highlighted less-appreciated issues of equity.

Dr London set out the arguments that support accelerated access to novel interventions: fairness, anti-paternalism, and reasonable risks. Dr London methodically analysed these principles and argued against the assumptions on which these are based; investigational medicines might be the best (or only) treatment for patients without established therapeutic options. While high regulatory requirements aim at safeguarding patients from unacceptable risks, this principle is self-defeating in situations where no therapeutic alternatives are available. Early access is therefore a win–win situation for populations without valuable alternative options, provided that this policy does not adversely affect drug development in other contexts.

Shortening the time to approval reduces the basis of evidence for both the efficacy and the safety of a medicine, and post-approval requirements (i.e. additional studies) are difficult to obtain. Consequently, rapid access might result in a longer time to generate the same amount of information that is required in a conventional approval process. In addition, to collect evidence in the clinical setting is less efficient than during clinical trials, and shifts the costs and risks from the marketing authorisation holder to the public.

Dr London concluded that:

1. Inequalities in access to effective interventions reflect inequalities in knowledge and information.
2. Accelerating access to investigational agents does not remove inequalities in health information and could aggravate them.
3. A high rate of intervention failure is to be expected in accelerated access but maximising what we learn from failure is key to closing information gaps and creating effective interventions where none currently exist, as well as closing information gaps between trial populations and real-world patients.
4. Pharmacovigilance will play an increasingly important role in preserving the integrity of the health information economy.

A lively discussion followed this talk drawing examples and perspectives from different settings in Switzerland, the Netherlands, Sierra Leone, France, and USA. The audience brought its cases and examples of the needs of severely-ill patients, general patients, and the ethics of standardised clinical trials and compassionate clinical trials.

Deployment of pharmacovigilance during mass drug administration in Sierra Leone

Wiltshire Johnson, Registrar & CEO, Pharmacy Board of Sierra Leone, Sierra Leone

Mr Johnson talked about the recent Ebola public health emergency in Sierra Leone. With first-hand experiences and storytelling he helped the audience better understand what it means for a developing country to go through such a health crisis. Pharmacovigilance during the Ebola crisis meant not only the safety surveillance of experimental treatments, but also of medical products such as disinfectants, rubber gloves, and other indispensable equipment, as well as surveillance of the antimalarial mass drug administration that needed to be rolled out at the same time.

The challenges faced in such contexts support the view that the traditional pharmacovigilance model and definition – which WHO defines as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems – may need to be redrawn to meet developing countries' needs. Mr Johnson demonstrated how challenging pharmacovigilance is in an environment where medicines are not always available or – when they are – mostly self-medicated due to inadequate diagnostic facilities, health workforce, and infrastructure.

Mr Johnson described what the health system in Sierra Leone had to handle during the Ebola crisis, listed the factors that lead to such a rapid spread of the infection, and the ensuing necessary interventions. He illustrated how the treatment of other conditions, such as malaria, pneumonia, and diarrhoea had become very difficult, due to the population's reluctance to seek medical help; many feared that the similarity of the unspecific symptoms that these diseases display to those of Ebola would prevent them from returning home. A mass administration of antimalarials became necessary, which in turn required intensified safety monitoring and thus further stretched all capacity.

Mr Johnson concluded by arguing that the idea that pharmacovigilance is a luxury should be replaced by a realisation that it is an essential system for the rational, safe, and cost effective use of medicines. This is the case in all countries and consequently for the benefit of the all public health systems. Pharmacovigilance should no longer be promoted as a "science" but as a "culture that deploys the use of science", Mr Johnson said.

The discussion that followed emphasised the importance of trust, truth, standards, advocacy and accountability in pharmacovigilance, and the enormous differences in the diverse scenarios where pharma-covigilance practices take place around the world.

Drug repurposing: Benefits and risks in using existing medicines in new indications

Dr Noel Southall, Research Scientist, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health (NIH), USA

Dr Noel Southall, research scientist at NIH's National Center for Advancing Translational Sciences (NCATS), gave a presentation on drug repurposing and what the field could learn from the science of pharmacovigilance.

The main objective of drug repurposing is to find ways to use approved drugs or discarded clinical candidates in the treatment of new diseases. Dr Southall used thalidomide as an example: this product was first approved in Germany in 1957 as a sedative and to treat morning sickness in pregnant women, but was removed from the market after a few years as it emerged that it caused birth defects. After that, thalidomide was explored in the context of leprosy and cancer. In 1999 it emerged that it was indeed very useful to treat multiple myeloma, and in 2005 the FDA approved using lenalidomide to treat this type of cancer and in 2006 thalidomide for the treatment of multiple myeloma and leprosy.

The steps required in this repurposing process are the identification of a possible new use for a specific drug, a proof of concept, the exploration of the new biologic environment related to the new use and, finally, the development of new products. Dr Southall illustrated this process with three study cases: auranofin, a gold-containing compound approved for the treatment of rheumatoid arthritis being explored in the context of chronic lymphatic leukaemia; chlorcyclizine, an antihistaminic being tested for antiviral use; and cyclodextrin, being investigated on its ability to target cholesterol and prevent neurodegeneration in diseases such as Niemann Pick.

"The idea is that sometimes when we learn something about a drug, it's true that it can cause a safety issue in one context, but those issues can be exactly therapeutic in a very different context," Dr Southall explained. The very same mechanism that made thalidomide cause birth defects in babies – the inhibition of angiogenesis – has a therapeutic effect against cancer in that it prevents further tumour growth by blocking the development of blood vessels.

When talking about what his field could learn from pharmacovigilance, Dr Southall mused that the infrastructure used for adverse event reporting could be applied to the efficacy event reporting of drugs, thus generating information on potential further uses in analogy to the signal detection process in pharmacovigilance. Dr Southall is involved in two projects that touch upon this: GINas (Global INgredient Archival System), a global substance database that aims to define and index substances in medical products; and CURE (Collaborative use repurposing engine), which aims to use existing drugs in new ways for infectious diseases lacking adequate treatment.

Rapid Fire talks

Six speakers shared an hour of the programme to each present a five-minute Rapid Fire talk. They covered a broad range of topics, such as the study of molecular structures to predict severe adverse drug reactions, and the value of VigiBase in real-time surveillance.

Drug structures that cause Stevens-Johnson syndrome
Tomas Bergvall, Research Engineer, Uppsala Monitoring Centre, Sweden

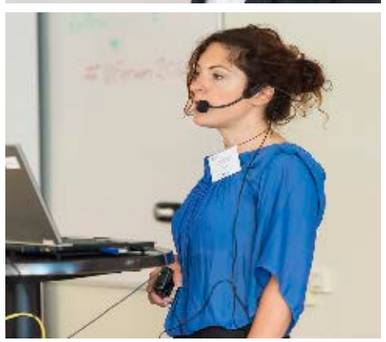
Finding real-time adverse drug reactions in VigiBase
Dr Rebecca Chandler, Medical Doctor, Uppsala Monitoring Centre, Sweden

The puberty of a medicine
Dr Agnes Kant, Director, Lareb, Netherlands

Application of STAMP (System-Theoretic Accident Model and Processes) for pharmaceutical safety, a.k.a. 'Plan B'
Dr Brian Edwards, Principal Consultant, Pharmacovigilance & Drug Safety, NDA Regulatory Science, UK

Rapid release of safer drugs for TB and MDR-TB: lessons learned from NIH-sponsored international clinical trials
Dr Jing Bao, Medical Officer, National Institute of Allergy and Infectious Diseases, USA

Exposure related variables and how they influence the occurrence of safety issues post approval
Alexandra Pacurariu, Pharmacovigilance Assessor, Medicines Evaluation Board, Netherlands



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The conceptualisation of an effective and safe Ebola vaccine in the midst of a pandemic

Dr Andrea Marzi, Staff Scientist, National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), USA

Virologist Dr Andrea Marzi gave a presentation focused on her involvement in developing the live-attenuated Ebola vaccine VSV-EBOV. The talk also drew on her field experience of running Ebola diagnostics tests in Monrovia, Liberia in 2014, during the West African Ebola outbreak, and outlined differences between the most recent Ebola outbreak and the one in 1976, which was caused by a more virulent strain than the one identified in 2014.

Dr Marzi illustrated different animal models and compared the advantages and disadvantages of approaches used in the development of Ebola vaccines. The live attenuated vaccine Dr Marzi and her colleagues developed has been developed on a vesicular stomatitis virus (VSV) vaccine platform, as VSV is an animal but not a human pathogen. The vaccine was later included in a largely successful ring-vaccination trial in Guinea. To date, the VSV-EBOV vaccine appears to offer protection about 10 days after immunisation with one injection. VSV-EBOV does not cause disease in livestock. It's efficient in immunocompromised people such as those suffering from HIV/AIDS, and the vaccine's efficacy is not affected by pre-existing immunity in humans against the VSV backbone.

Challenges during the clinical phase of the vaccine development were related to the lack of control groups – needless to say it is not morally defensible to give groups at high risk of infection a placebo – and to the number of participants in the trial naturally drying out faster the more successful the vaccine is.

Dr Marzi also pointed out that Ebola vaccines have been in the pipeline for a very long time, but it has taken the recent crisis for anyone to take enough interest to fund and complete the development of a vaccine. This highlights another issue of the pharmaceutical industry, namely how a disastrous disease such as Ebola can be neglected for decades due to its relatively rare occurrence, and the consequent lack of return on investment.

WHO lists ten viral diseases that should be prioritised, Dr Marzi said, but funding needs to be secured to develop treatments. As the main global health concern has shifted from the Ebola outbreak to Zika virus-induced disease, which exploded in Latin America during 2015, funding also shifts away from Ebola vaccine research to other, more urgent viral outbreaks.

The conference attendees heard more about pharmacovigilance in West Africa on the second day of Uppsala Forum, when Wiltshire Johnson, CEO and Registrar at Pharmacy Board of Sierra Leone, gave a lecture that touched upon some areas that Dr Marzi had discussed.

When the heat is on: A debate on real-time, real-life drug surveillance

Dr Alex Dodoo, Director, WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance, Ghana

Prof Ralph Edwards, Senior Advisor & Professor of Medicine, Uppsala Monitoring Centre, Sweden

Accelerated access to medicines would inevitably raise new and serious safety issues that current systems are poorly equipped to manage. Low income countries with weak regulatory and pharmacovigilance resources are already vulnerable to the risks of medicines approved in faraway places for different populations; new medicines with a thinner safety profile would provide even more risk for them. So-called advanced regulatory and pharmacovigilance systems are sluggish and bureaucratic and are far from being fit for optimum management and surveillance even of medicines in general, but especially of those with an uncertain safety profile. In the debate, pharmacovigilance was characterised as having located itself in a passive spot and being something of a closed shop; a more visible, active engagement is needed with pharmacovigilance driving the safety movement and rising to new challenges such as rapid access to new drugs.

A new paradigm is required, maybe based on the practice of oncologists and neurologists whose attention to patients and their responses to therapy, including side effects, demonstrates safety surveillance embedded in clinical practice. Physicians should follow up patients and engage them in the enterprise of medicines safety. Great benefits would flow from the sharing of data and decisions with a wide range of stakeholders, especially patients, and establishing their priorities.

The modern world demands greater speed in relation to everything; medicines should not be excluded, though the humane impulse to treat, especially ignored or orphan diseases, must not give rise to harm and loss of confidence. Globally, IT patient management systems must have software that reminds and facilitates reporting of bad outcomes of therapy. Existing platforms could be reformed; lawyers and others re-educated; stakeholders galvanised; clinicians engaged; and promising new medicines could be released earlier than the elaborate, precautionary systems currently permit.

> "What's required is for everything to move faster, more efficiently, and not be stuck in past paradigms."
>
> *– Prof Ralph Edwards*

Assessing the impact of pharmacovigilance: Predictors and correlates

Dr Gerald Dal Pan, Director, Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, US Food and Drug Administration (FDA), USA

Dr Gerald Dal Pan addressed the question of how to find out if a pharmacovigilance system achieves its goals efficiently, whether resources are well allocated, and whether the impact on public health is beneficial.

When assessing the impact that pharmacovigilance activities may have – such as regulatory changes, label changes, and prescription changes – we need to look at process measures and knowledge measures, which are generally easier to assess; also at behaviour measures and health outcome measures, which are often harder to assess.

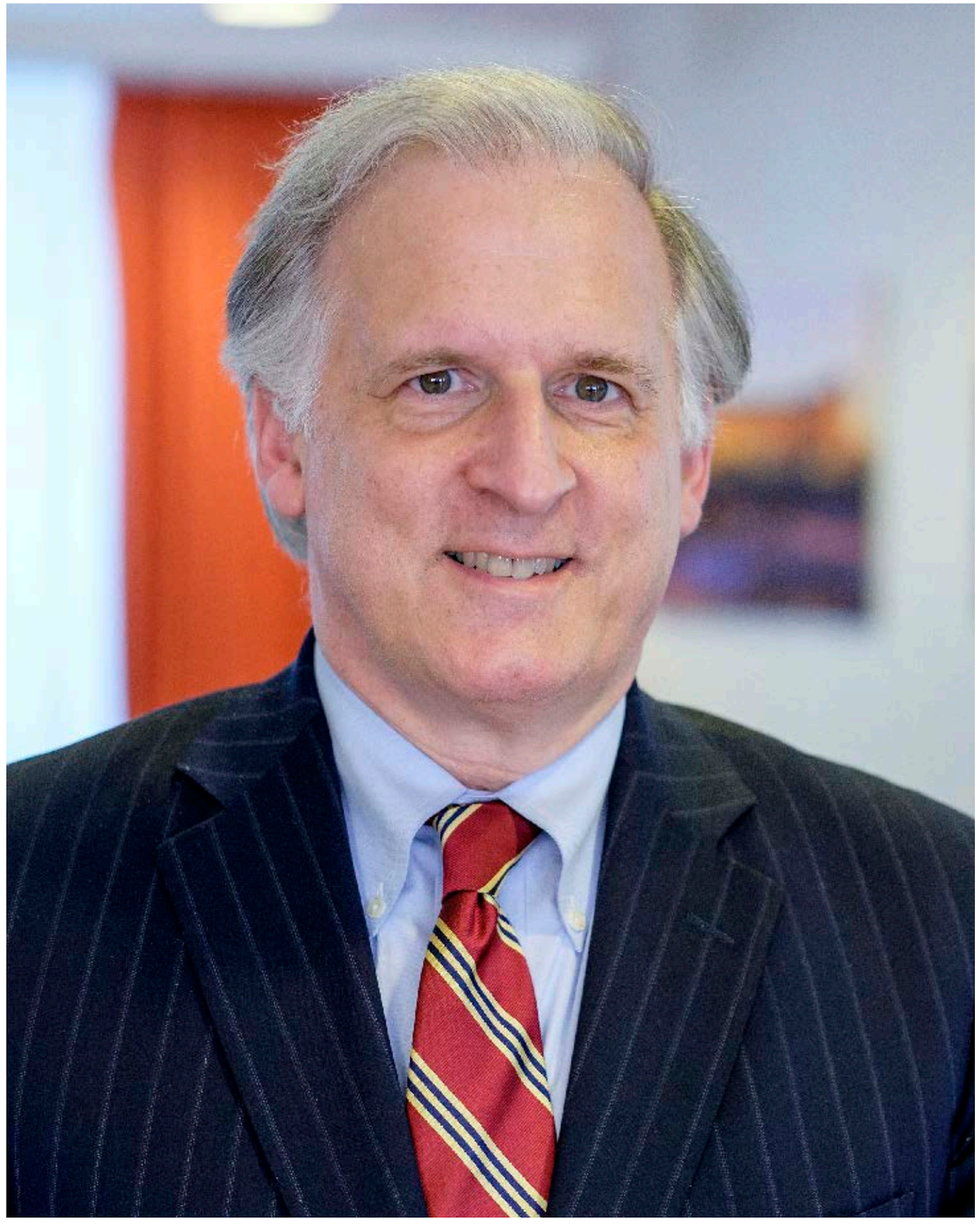
Drawing on his experience at the US-FDA, Dr Dal Pan discussed some common challenges to both identifying the issues with the potentially problematic drugs, and assessing what impact any actions by the regulator have had.

He presented several initiatives the US-FDA has undertaken to assess the impact of their pharmacovigilance system. Of note was that half of all label changes related to safety concerns were triggered by spontaneous reports, which underlines the value of a spontaneous reporting system. Among the challenges in assessing spontaneous reports is the difficulty of identifying the marketing authorisation holder if only the active ingredient is reported when both a brand and a generic version is available.

Dr Dal Pan presented an example of how the FDA has assessed the impact of regulatory action. Action had been taken regarding the use of cisapride in 1998, when contraindications for treatment were added to the product information. An evaluation of prescribing patterns, comparing prescriptions one year before and one year after a "Dear Health Care Provider Letter" was sent out to inform practitioners about these new precautions to be taken, showed no difference.

The US-FDA has also looked into how well drug safety risks are communicated to the public, by measuring patients' knowledge of the risks associated with their own medicines. In a survey, only about 30% of the respondents could demonstrate a sufficient level of knowledge – pointing towards a need to improve medication information for patients.

Dr Dal Pan also referred to the publication "PRAC strategy on measuring the impact of pharmacovigilance activities" – released in January 2016 by the Pharmacovigilance and Risk Assessment Committee (PRAC) of the European Medicines Agency (EMA) – as an example of other agencies' work to assess the impact of pharmacovigilance.



Uncertainty and examples of reimbursement issues with accelerated release of drugs

Dr Dyfrig Hughes, Professor of Pharmacoeconomics &
Co-director, Centre for Health Economics and Medicines Evaluation,
Bangor University, UK

Professor Dyfrig Hughes introduced the different early-access medicines schemes in the United Kingdom and discussed issues surrounding cost effectiveness in public health systems.

As populations age, technology advances, and the burden of chronic diseases increases, the demand for healthcare is infinite. All the while resources – such as financing, physicians, and facilities – are scarce. Those factors mean that choices have to be made and some therapies must be prioritised over others, Dr Hughes said.

A dilemma in this scenario is to decide between spending money on expensive but crucial therapies that only a few patients can benefit from, or instead investing these resources on more broad and generally applicable healthcare services. "Do you deny patients the benefits of these particular treatments because they are not cost-effective, or do you deny other patients cheaper and more far-reaching healthcare programmes?" Prof Hughes pondered.

When considering costs, not only the direct medical ones to the healthcare system must be taken into consideration, but also the ones borne by the patients and their family, as well as the economic impact the choice of treatment has on the productivity of the patients, when they have to stay away from work. Cost-effectiveness calculations must take the patients' quality of life into account.

Drawing upon examples from the United Kingdom, Prof Hughes presented several initiatives and ways to allow early access to medicines, all aiming at making novel medicines available to patients with little or no other therapeutic options, even when the clinical development may not be yet completed. These include PRIME (PRIority MEdicines); accelerated access; conditional marketing authorisation; adaptive pathways; compassionate use; and Promising Innovative Medicine (PIM – a programme run by MHRA).

The restricted data set available when the development and approval of medicines is fast-tracked increases the uncertainty of a cost-effectiveness calculation. Also open to discussion is the question if, in the light of such uncertainty, the high cost of such medicines should not be borne by the marketing authorisation holder instead of the healthcare system.

> "Do you deny patients the benefits of particular treatments on behalf of them being not cost-effective, or do you deny other patients cheaper and more far-reaching healthcare programmes?"

Accelerated release of HIV medicines: The challenges of a manufacturer

Andreas Palmborg, Medical Advisor,
Janssen Pharmaceuticals, Sweden

Janssen's infectious diseases portfolio and pipeline includes hepatitis, HIV, respiratory diseases, and pathogens of global concern. The company's strategic focus is on three core areas, with an exploratory platform in addition: to end preventable child and maternal mortality; to ensure that children are born HIV-free and those living with the disease have access to affordable medicines; and to eliminate XDR/MDR-TB and simplify regimens. Their exploratory platforms are based on a commitment to develop and deliver innovative technology to address key global challenges such as vaccines for HIV and Ebola and treatments for neglected tropical diseases.

In their portfolio of three HIV treatments, the focus is sustainable HIV-drug access and appropriate use of medicines in resource-limited countries, and novel routes of delivery. Access and differential pricing, license agreements for generic versions, and priority registration filings were among critical activities, while clinical training and support and participation in the WHO Accelerated Registration Pilot in Africa were taking place to support rapid access and appropriate use.

The company's response to the great global burden of TB was the ground-breaking drug Bedaquiline, a new class of anti-TB compounds, given accelerated approval by the US-FDA in 2012 and approved in many jurisdictions since. Because of an increased mortality risk as compared with placebo in Phase II trials, and according to WHO guidelines, Bedaquiline is approved only for patients who have shown resistance to other TB medications, have been through a thorough process of informed consent, and need to be under active surveillance. The Janssen Access & Affordability Strategy seeks to assure sustainable access to the drug and includes a four-year donation programme of 30,000 treatments. Pharmacovigilance will be provided by partners in low- and middle-income countries.

"When looking at epidemiology numbers for HIV, in several parts of the world we see some quite encouraging results when it comes to access to treatment, but in many places one group that's lagging behind is women – especially young women."

Sharing the burden: How can marketing authorisation holders support infrastructures needed with accelerated release of medicines?

Ingela Larsson, Cross Sector Country Safety Team Lead Baltics & Nordics, Janssen Pharmaceuticals, Sweden

The highest level ethical practice in pharmaceutical manufacturing is still driven by the Declaration of Helsinki. A high priority is reviewing and improving pharmaceutical skills and processes, including on-time delivery of medicines to clinical trials, refining the demanding and complex issues associated with informed consent, and protecting vulnerable patients such as children or the frail elderly.

Janssen is currently managing worldwide trials for the Type II Diabetes drug Invokana (canagliflozin) on six continents (Phases I to III); XDR/MDR-TB drug Sirturo (bedaquiline) on five continents (Phase I to III); and an Ebola vaccine (Ad26.ZEBOV) on three continents. Finding patients, mobilising resources, defining protocols and devoting time to monitoring source data and performance are all major challenges.

> "Nowadays we get a shipment of blood samples, and within 24 hours we have data in our databases; we have the oversight of data and safety information readily available… This has significantly improved the timeline for clinical trials."

Janssen's contribution to supporting infrastructures for accelerated release include:

- Working with local stakeholders in health care, authorities and academia.
- Training and using local HCPs in investigational centres.
- Training and using local site managers in clinical trial monitoring.
- Focusing on high standards in clinical trials so as not to jeopardise patient safety.
- Building and connecting with modern infrastructure:
  - IT
  - Logistics for distribution

Janssen has offered donated drugs on compassionate grounds (e.g. Romania), and has discussed pricing policy with patient organisations and negotiated with them to fund education. The UNITAID Medicines Patient Pool Initiative was an opportunity of interest in the search for new relationships and marketing contracts with other companies and organisations.

Closing remarks

Dr Ola Caster, Senior Researcher, Uppsala Monitoring Centre, Sweden

The meeting focused on the desirability of rapid access to drugs, the practical and theoretical challenges, the social and individual benefits and harms, and the role that reformed pharmacovigilance might play in supporting optimal use of new medicines. The topics were extensively and frankly discussed with vivid evidence and experience presented.

Among new developments, the identification of chemical entities with a predisposition to cause harm and the fruits of pharmacogenetics in recognising groups with specific vulnerabilities were mentioned as important developments in the pursuit of reducing harm.

The similarities and parallel flows in pharmacovigilance and in drug repurposing were discussed with their common characteristics of clinical observation and suspicion, offering the basis for a potentially productive shared vision. The engagement of regulatory pharmacovigilance at a much earlier stage in drug development was proposed as one measure with possible benefits.

Ideas for reformed pharmacovigilance were proposed: one was for a much bolder, high-profile engagement with society and the establishment of a lively joint enterprise with reciprocal obligations; another for an active, decentralised system with regulated responsibilities for all players. Evidence was presented of the rich contribution patients can make and their under-representation in many collaborations and decision-making forums. The question of the high cost of some new drugs was a major issue, with manufacturers, payers and patients sometimes having a very different view of priorities.

Idelalisib and Bedaquiline were cited as two notorious rapid-access drugs, the former a failure, the latter still a matter of controversy. The serious risk to public confidence and trust, when things go wrong, was emphasised.

The balance of opinion in the meeting was in support of rapid access to specific, well-chosen drugs, but with the clear proviso that regulatory and pharmacovigilance systems had an over-riding obligation to minimise harm, and to guarantee that novel, agile and robust measures had to be explored and implemented.

Uppsala Forum 2018

We are planning to meet again in 2018 – more information will follow on our website: www.who-umc.org. For further information, please contact: globalcomms@who-umc.org.

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About Uppsala Monitoring Centre

Uppsala Monitoring Centre advances the science of pharmacovigilance and inspires patient safety initiatives all over the world. As an independent, non-profit foundation, we engage stakeholders who share our vision and collaborate to build a global patient safety culture.

As a leader in the research and development of new scientific methods, we explore the benefits and risks of medicines to help minimize harm to patients, and offer products and services used by health authorities and life-science companies worldwide.

Our unique expertise makes us an organisation with the capacity to transform patient safety from an ambition into a reality.

For almost 40 years, we have provided scientific leadership and operational support to the WHO Programme for International Drug Monitoring, expanding the global pharmacovigilance network to reach more than 95% of the world's population.

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